SEP 14 2006

K060762

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Aesculap PEEK VBR System
20 March 2006

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Matthew M. Hull
800-258-1946 (phone)
610-791-6882 (fax)

TRADE NAME: Aesculap PEEK VBR System

COMMON NAME: Vertebral Body Replacement Device

CLASSIFICATION NAME: Spinal Vertebral Body Replacement Device

REGULATION NUMBER: 868.3060

PRODUCT CODE: MQP

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Aesculap PEEK VBR System is substantially equivalent to:

1) PEEK Tetris Spinal Implant by Signus Medical LLC (K031757)
2) Curved PEEK Tetris Spinal Implant by Signus Medizintechnik (K041888)
3) Rabea Spinal Implant by Signus Medizintechnik (K043316)
4) Semial Spinal Implant by Signus Medical (K051659)
5) Nubic Spinal Implant by Signus Medical ((K052096)
6) Novel VBR Spinal System by Alphatec/ Nexmed (K042201)
7) Stryker Spine AVS PEEK Spacers (K042571) and (K051205)

DEVICE DESCRIPTION

The Aesculap PEEK VBR System is a vertebral body replacement device that is implanted into the vertebral body space to improve stability of the spine. Components are offered in a variety of shapes and sizes to meet he requirements of the individual patient anatomy. Components are manufactured from PEEK – Optima (per ASTM F2026).

INDICATIONS FOR USE

The Aesculap PEEK VBR System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK VBR System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK VBR System implants can be used individually or in pairs. The Aesculap PEEK VBR System is also intended for use with bone graft.

TECHNOLIGICAL CHARACTERISTICS(compared to Predicate(s))

The components of the Aesculap VBR System are offered in a similar range of shapes and sizes as the predicate devices. The material used for the Aesculap device is the same as that used to manufacture the predicate devices.

PERFORMANCE DATA

Static and dynamic testing of the Aesculap VBR System was performed in accordance with ASTM F 2077 and/or F1717 as recommended by the FDA Guidance for Spinal System 510(k)'s.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2006

Aesculap, Inc.
% Mr. Matthew M. Hull
Regulatory Affairs Manager
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K060762
Trade/Device Name: Aesculap PEEK Vertebral Body Replacement (VBR) System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: August 10, 2006
Received: August 11, 2006

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchner for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K060762

Device Name: Aesculap PEEK Vertebral Body Replacement (VBR) System

Indications for Use:

The Aesculap PEEK Vertebral Body Replacement (VBR) System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK VBR System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK VBR System implants can be used individually or in pairs. The Aesculap PEEK VBR System is also intended for use with bone graft.

Prescription Use ____X____ and/or Over-the-Counter Use ______________
(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehn
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K060762